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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Telehealth for Acute and Chronic Care Consultations.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public to inform our review on *Telehealth for Acute and Chronic Care Consultations*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to the Public Health Service Act.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address:

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FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Telehealth for Acute and Chronic Care Consultations*.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies

conducted). We are looking for studies that report on *Telehealth for Acute and Chronic Care Consultations*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: <https://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2434>

This is to notify the public that the EPC Program would find the following information on *Telehealth for Acute and Chronic Care Consultations* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
 - *For completed studies that do not have results on ClinicalTrials.gov*, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute ALL Phase II *and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request.

Materials submitted must be publicly available or able to be made public.

Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at:

<https://www.effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

KQ 1: Are telehealth consultations effective in improving clinical and economic outcomes?

Telehealth consultations can be for any acute or chronic clinical condition across any specialty ranging from infectious disease to psychiatry.

Clinical and economic outcomes may include, but are not limited to, mortality and morbidity, utilization of health services, cost of services, and access to services.

KQ 2: Are telehealth consultations effective in improving intermediate outcomes?

Intermediate outcomes include both outcomes that precede the ultimate outcomes of interest and secondary outcomes.

Intermediate outcomes may include, but are not limited to, patient and provider satisfaction, behavior, and decisions (e.g., patient completion of treatment, provider antibiotic stewardship); volume of services; and health care processes (e.g., time to diagnosis or treatment).

KQ 3: Have telehealth consultations resulted in harms, adverse events, or negative unintended consequences?

What are the characteristics of telehealth consultations that have been the subject of comparative studies?

The characteristics include:

- a) Clinical conditions addressed. These can include broad categories such as diagnosis and treatment of infectious disease or specific conditions (e.g., upper respiratory infection, hepatitis C, skin infections) or decisions (e.g., stewardship of antibiotics or antimicrobials, selection of treatments)

- b) Characteristics of the providers and patients involved
- c) Relationships among the providers and patients involved including whether these are new or ongoing relationships
- d) Telehealth modalities and/or methods for sharing patient data used
- e) Whether specifics in (d) meet Medicare's coverage and HIPAA requirements
- f) Settings including
 - Type of health care organization including the organizational structure (e.g., integrated delivery system, critical access) and the type of care (e.g., long-term care, inpatient, ambulatory care)
 - Country
 - Geographic and economic characteristics such as urban or rural areas, or areas with high vs. low socioeconomic resources
- g) Other circumstances (e.g., appropriate transportation, climate)
- h) Payment models or requirements or limits for payment including
 - The payer/insurance for the patient (e.g., Medicare, Medicaid, commercial)
 - Any parameters for payment (e.g., relative value units [RVUs]) or limits on visits
 - Any eligibility requirements for payment based on patient, provider, setting or context characteristics

KQ 5: Do clinical, economic, intermediate, or negative outcomes (i.e., the outcomes in Key Questions 1, 2, and 3) vary across telehealth consultation characteristics (Key Question 4)?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Populations

- Patients of any age, with medical care needs for prevention, treatment, or management of chronic or acute conditions
- Providers (clinicians or health care organizations)
- Payers for health care services (public, private, insurers, patients)

Interventions

- Telehealth consultations are defined as the use of telehealth designed to facilitate collaboration among providers, often involving a specialist, or between clinical team members, across time and/or distance, on the assessment, diagnosis, and/or clinical management of a specific patient or group of patients.
- Telehealth consultations can be for any acute or chronic conditions. The search will be both general as well as focused on conditions identified as areas of growth and policy interest such as infection, disease, dermatology, and critical care.
- Telehealth consultations can use any technology (e.g., real-time video, store and forward).

Comparator

Other locations, patients, or time periods that use in-person consultations or provide usual care (which could include no access to specific services)

Outcomes for Each Key Question

Key Question 1: Clinical and economic outcomes

- Clinical outcomes such as mortality, morbidity, function, recovery, infection, and access to services
- Economic outcomes such as return on investment, cost, volume of visits, and resource use

Key Question 2: Intermediate outcomes

- Patient satisfaction, behavior, and decisions such as completion of treatment, or satisfaction with less travel to access health care
- Provider satisfaction, behavior, and decisions such as choice of treatment or antibiotic stewardship
- Time to diagnosis and time to treatment
- Diagnostic concordance or other measures of agreement between in-person and telehealth consultations

Key Question 3: Adverse effects or unintended consequences

- Loss of privacy or breach of data security
- Misdiagnosis or delayed diagnosis
- Inappropriate treatment
- Increase in resource costs, negative return on investment

Key Question 4: Not applicable (this is a descriptive question)

Key Question 5: Clinical and economic outcomes (see Key Question 1), intermediate outcomes (see Key Question 2), and adverse effects or unintended consequences (see Key Question 3).

Timing

- Telehealth consultations can be used at any point in the diagnosis, treatment, or management of a patient.
- Outcome measurement needs to occur after the telehealth consultation.

Setting

The consultation can involve providers and patients in any location. These could include inpatient, outpatient, or long-term care, and could be in civilian, Veterans Administration, or military facilities.

Study Designs

- Comparative studies, including trials and observational studies.
- Descriptive studies may be used to inform the decision model as needed but will not be included in the systematic review.

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Acting Director

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